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Display Date 11-3-04
Publication Date 11-4-04
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. ~~2004N-0087~~] 2004D-0460

Draft Guidance for Industry on Listed Drugs, 30-Month Stays, and Approval of Abbreviated New Drug Applications and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers." This draft guidance follows the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) (MMA) on December 8, 2003. In part, this guidance satisfies FDA's obligation under that law to clarify the definition of "listed drug" for persons who wish to submit a change (i.e., an amendment or supplement) to an abbreviated new drug application (ANDA). The guidance explains when a change to an application should reference a drug different from the drug listed in the original ANDA, requiring the change to be made through an entirely new application.

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In addition to the definition of "listed drug," the draft guidance clarifies certain other provisions of the MMA that significantly change the law that existed before the MMA's enactment. These include changes regarding 30-month stays and approval of ANDAs and new drug applications submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (505(b)(2) applications). The draft guidance also explains the effective dates that apply to the MMA's provisions.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Martin Shimer, Center for Drug Evaluation and Research (HFD–615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855 301–827–5710.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2)

Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers." On December 8, 2003, the MMA was signed into law. Among other things, Title XI of that law, "Access to Affordable Pharmaceuticals," states that guidance will be issued to define the term "listed drug" with respect to amendments and supplements to ANDAs. This guidance is necessary because the MMA specifies that, "An applicant may not amend or supplement an [ANDA] to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary" (MMA, Title XI, section 1101(a)(1)(B)). In part, the draft guidance clarifies the definition of "listed drug" in the context of ANDAs as directed by the MMA. Portions of the guidance addressing "listed drug" are expected to be of use to sponsors who are contemplating submitting an amendment or supplement to an existing ANDA rather than submitting a new application. The draft guidance should aid these sponsors in determining when to reference a different listed drug and, thus, when to submit a new application rather than an amendment or supplement. A situation that is not considered in this guidance is that where a pending ANDA was submitted referencing a petition approved under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(2)(C)), and another application is approved for the product described in the petition before the pending ANDA is approved. FDA has not completed its analysis of this situation, and therefore the draft guidance does not cover it.

In addition to the definition of "listed drug," the draft guidance clarifies certain other significant changes made by the MMA to provisions of the act that were originally added by the Drug Price Competition and Patent Term

Restoration Act of 1984 (Public Law 98–417) (Hatch-Waxman). These include changes made by the MMA with respect to the availability and termination of 30-month stays of approval on ANDAs and 505(b)(2) applications under section 505(j)(5)(B)(iii) and 505(c)(3)(C) of the act, respectively, and to requirements for notice of patent certifications described by section 505(b)(2)(A)(iv) and 505(j)(2)(A)(vii)(IV) of the act (paragraph IV certifications). The draft guidance also clarifies the applicability of certain changes made by the MMA regarding the period described by section 505(j)(5)(B)(iv) of the act during which ANDAs with paragraph IV certifications that were not the first to be submitted cannot be approved (180-day exclusivity). Finally, this guidance explains the effective dates that apply to the MMA's amendments. FDA is aware that these changes are complex and include significant departures from previous law. The agency therefore wishes to provide guidance to industry to clarify these amendments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the definition of "listed drug" for amendments and supplements to ANDAs, and on 30-month stays and certain other matters related to the approval of ANDAs and 505(b)(2) applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

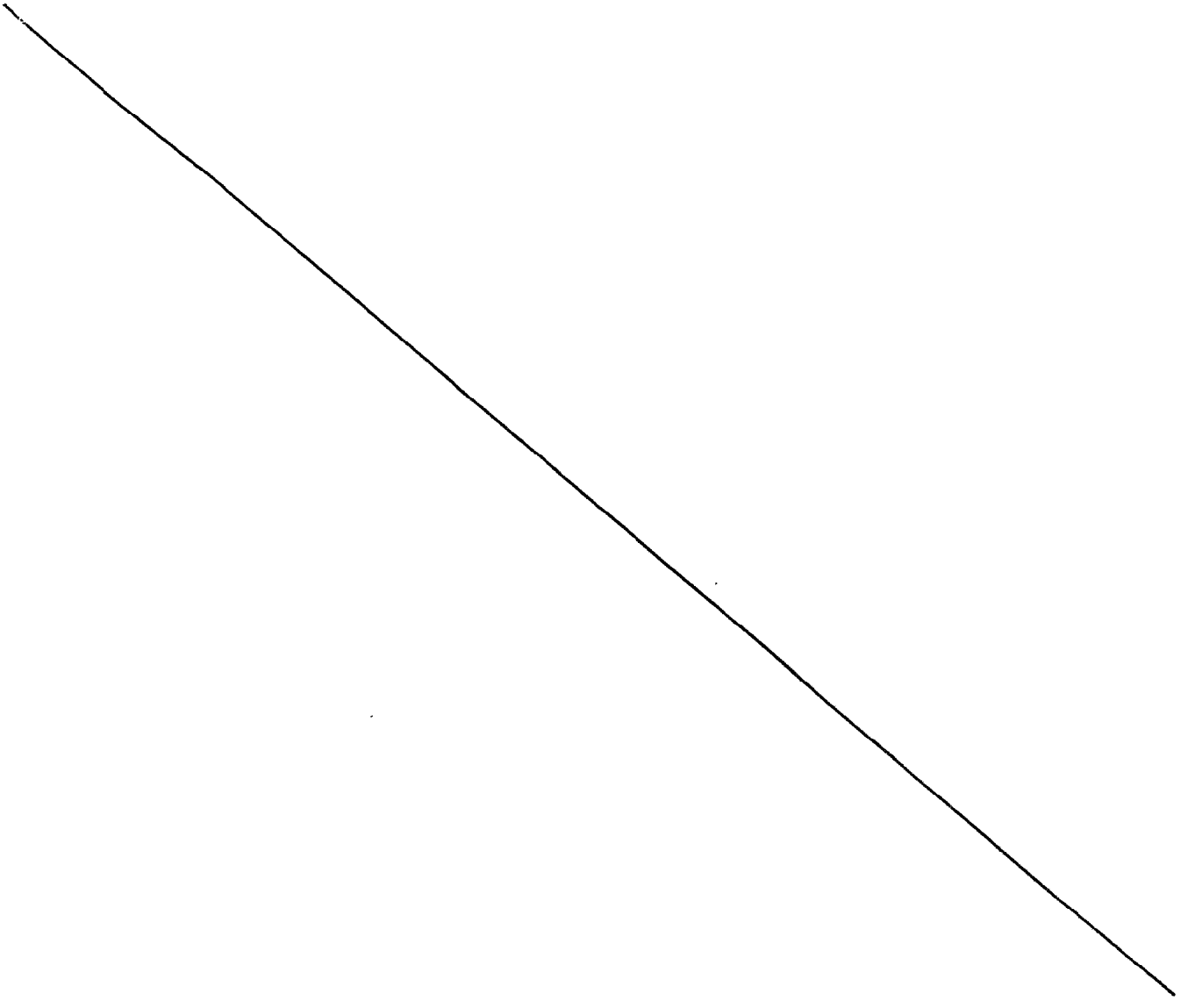
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit

one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*



Dated: 10/18/04

October 18, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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